510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien LP (formerly registered as Tyco Healthcare, LP) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5000
CONTACT PERSON:	Angela Van Arsdale Associate, Regulatory Affairs Phone: (203) 492-5496 Fax: (203) 492-5029
DATE PREPARED:	October 30, 2009
TRADE/PROPRIETARY NAME:	SILS™ Port
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and/or accessories
PREDICATE DEVICE(S):	Covidien SILS™ Port (K082619) Dexide Trocar (K981941)
DEVICE DESCRIPTION:	Three laparoscopic trocars and an insufflation tube bound by a flexible port.
INTENDED USE:	The SILS™ Port is indicated for multiple instrument or camera access to the abdominal cavity through a single incision for performing minimally invasive laparoscopic procedures.
TECHNOLOGICAL CHARACTERISTICS:	The SILS™ Port provides the ability to use three conventional laparoscopic trocars and an insufflation port through a single incision while providing the ability to maintain pneumoperitoneum.
MATERIALS:	All components of the SILS™ Port are comprised of materials that have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices -- Part 1: Evaluation and Testing.
PERFORMANCE DATA:	In-vitro and in-vivo testing has been performed in support of the intended use of this device.

DEC - 3 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Covidien LP
% Ms. Angela Van Arsdale
Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

DEC - 3 2009

Re: K093372
Trade/Device Name: SILS™ Port 15mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 24, 2009
Received: November 25, 2009

Dear Ms. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: SILS™ Port 15 mm

Indications for Use:

The SILS™ Port is indicated for multiple instrument or camera access to the abdominal cavity through a single incision for performing minimally invasive laparoscopic procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen D. Burns for NRO
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093372